FINTEPLA REMS

Fintepla®
(fenfluramine) CIV
2.2 mg/mL oral solution

Pharmacy Guide

This guide describes the requirements of the FINTEPLA REMS and the responsibilities of pharmacies. For more information regarding the FINTEPLA REMS, please visit www.FinteplaREMS.com or call 1-877-964-3649.

Fintepla®
(fenfluramine) CIV
2.2 mg/mL oral solution

What Is FINTEPLA?

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome in patients who are 2 years of age and older.

Risk of valvular heart disease and pulmonary arterial hypertension

Valvular heart disease and pulmonary arterial hypertension have been associated with fenfluramine. There is an association between serotonergic drugs with 5-HT2B receptor agonist activity including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension. In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-1.6% of patients taking FINTEPLA were found to have trace aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities.

Monitoring

- Prior to starting treatment, patients must undergo an echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypertension
- Echocardiograms must be repeated every 6 months while a patient is taking FINTEPLA
- If FINTEPLA is discontinued, a follow-up echocardiogram must be performed once 3 to 6 months after the final dose
- If valvular heart disease and/or pulmonary arterial hypertension is observed on an echocardiogram, then the prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA

What Is the FINTEPLA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. FINTEPLA is available only through a restricted distribution program called the FINTEPLA REMS because of the risk of valvular heart disease and pulmonary arterial hypertension.

What Are the FINTEPLA REMS Requirements?

- Healthcare providers must be certified in the REMS to prescribe FINTEPLA
- All patients must be enrolled in the REMS to receive FINTEPLA
- All pharmacies must be certified in the REMS to dispense FINTEPLA
- Before dispensing, pharmacies must obtain authorization to dispense by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive treatment
- Upon notice from the REMS, ALL pharmacies must provide complete and accurate requested REMS data such as patient, prescriber, prescription, and dispensing data on a timely basis but not longer than 15 calendar days. Inpatient pharmacies should provide the REMS with the patient's current dosing, quantity of FINTEPLA being dispensed at discharge, and discharge date by fax at 1-833-568-6198

How Does a Pharmacy Become Certified in the FINTEPLA REMS?

In order to become certified, the pharmacy must	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy 2. Have the authorized representative review this *Pharmacy Guide* and the *REMS Program Overview* 3. Have the authorized representative enroll in the REMS by completing the *Outpatient Pharmacy Enrollment Form* or *Inpatient Pharmacy Enrollment Form*, as appropriate, and submitting it to the REMS 4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using this *Pharmacy Guide*

What Are the Responsibilities of Outpatient Pharmacies?

Before dispensing	1. Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive the drug
To maintain certification to dispense	2. Have the new authorized representative enroll in the REMS by completing the *Outpatient Pharmacy Enrollment Form* if the authorized representative changes
At all times	3. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies 4. Maintain records that all processes and procedures are in place and being followed 5. Maintain records documenting staff's completion of REMS training 6. Maintain records of dispensing information including patient, prescriber, prescription, and dispensing data 7. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed

Phone: 1-877-964-3649 • www.FinteplaREMS.com • **Fax:** 1-833-568-6198

What Are the Responsibilities of Inpatient Pharmacies?

Before dispensing	1. For patients initiating treatment: Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive the drug 2. To continue maintenance therapy: Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the patient is under the care of a certified prescriber, the patient is enrolled, and the patient is authorized to receive the drug
At discharge	3. Dispense no more than 15 days' supply
To maintain certification to dispense	4. Have the new authorized representative enroll in the REMS by completing the *Inpatient Pharmacy Enrollment Form* if the authorized representative changes
At all times	5. Not distribute, transfer, loan, or sell FINTEPLA 6. Maintain records that all processes and procedures are in place and being followed 7. Maintain records that document staff's completion of REMS training 8. Maintain records of dispensing information for all patients, including the patient's current dosing, quantity of FINTEPLA being dispensed at discharge, and discharge date. Provide this information to the REMS via fax when the patient is discharged 9. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed 10. To order FINTEPLA, contact the REMS at 1-877-964-3649

Authorization to Dispense

To obtain authorization to dispense FINTEPLA, pharmacies can contact the REMS online using www.FinteplaREMS.com or by calling 1-877-964-3649. The REMS Coordinating Center will provide the patient's authorization status based on the prescriber's certification status, the patient's enrollment status, and the *Patient Status Form*. The prescriber completes and submits the *Patient Status Form* to the REMS before treatment initiation and every 6 months during treatment. The *Patient Status Form* provides documentation of the required echocardiogram monitoring and the prescriber's determination of appropriateness for treatment.

Authorized: The prescriber is certified, or the patient is under the care of a certified prescriber, the patient is enrolled, and the patient has a *Patient Status Form* on file with the REMS. The pharmacy may proceed with dispensing FINTEPLA.

Authorized—Warning: The prescriber is certified, or the patient is under the care of a certified prescriber, the patient is enrolled, and the patient has a *Patient Status Form* on file with the REMS that is overdue, but it is within the 90-day grace period. The pharmacy may proceed with dispensing FINTEPLA. The REMS Coordinating Center will contact the prescriber and patient to remind them of the required echocardiogram monitoring and that the *Patient Status Form* is overdue.

Not Authorized: The prescriber is not certified, the patient is not under the care of a certified prescriber, the patient is not enrolled, the patient does not have a *Patient Status Form* on file, the prescriber determined the patient is not authorized to receive FINTEPLA on the *Patient Status Form*, or the patient has a *Patient Status Form* more than 90 days overdue. Pharmacies must not dispense FINTEPLA to any patient with a status of "Not Authorized." Contact the REMS Coordinating Center at 1-877-964-3649 for assistance.

Additional Risks and Safety Information

The information presented in this guide does not include a complete list of all safety information for FINTEPLA. To review complete safety information on FINTEPLA, please refer to the Prescribing Information for FINTEPLA at www.FinteplaREMS.com.

To report adverse events, contact Zogenix, Inc. at 1-866-964-3649, or the FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Fintepla®
(fenfluramine) CIV
2.2 mg/mL oral solution

ZOGENIX

Phone: 1-877-964-3649 • www.FinteplaREMS.com • **Fax:** 1-833-568-6198